APR 0 8 2014

K133949

**TOP CALIBRE SDN. BHD.**

**FDA 510(k), Premarket Notification: 510(k) Summary**

**Date : April 01, 2014**

**1.0 Submitter:**

**Top Calibre Sdn. Bhd.**
Lot 13726, Jalan Haji Salleh,
Batu 5 ¼, Off Jalan Meru,
41050 Klang, Selangor,
Malaysia

Telephone No.: +603 3291 0516
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**2.0 Contact Person:**

Contact: Ms Rosnita Maodin
Telephone No.: +603 3291 0516
Fax No.: +603 3291 0542

**3.0 Name of Device:**

Trade Name(s) : Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs.
Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs.
Common Name : Powder-Free Nitrile Patient Examination Glove
Classification Name : Patient Examination Glove
Regulation Number : 21 CFR 880.6250
Classification Number: Class I
Product Code : 80 LZA, 80 LZC

**4.0 Identification of the Legally Marketed Device:**

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs, Class I Patient Examination Gloves, Nitrile – 80 LZA, Specialty – 80 LZC, meets all of the requirements of ASTM D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application.

Predicate Device: K091652, Nitrile Powder Free Examination Gloves (Blue) Tested for Use with Chemotherapy Drugs-VBLU

There are no different technological characteristics compared to the Predicate Device.

**5.0 Description of Device:**

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs meet all of the requirements of ASTM D6319-10.
The gloves are ambidextrous single-use disposable devices that come in five sizes (XS, S, M, L, XL) in blue or orange color.

**6.0 Intended Use of the Device:**

6.1 Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
This glove has been tested for use with specific chemotherapy drugs listed below.

**Chemotherapy Drug Permeation**
**(Minimum Breakthrough Detection Time in Minutes)**

| | |
|---|---|
| **Carmustine (BCNU) (3.3 mg/ml)** | 15.1 |
| Cisplatin (1.0 mg/ml) | >240 |
| Cyclophosphamide (Cytoxan) (20 mg/ml) | >240 |
| Cytarabine (100 mg/ml) | >240 |
| Dacarbazine (DTIC) (10.0 mg/ml) | >240 |
| Doxorubicin Hydrochloride (2.0 mg/ml) | >240 |
| Etoposide (20.0 mg/ml) | >240 |
| Fluorouracil (50.0 mg/ml) | >240 |
| Ifosfamide (50.0 mg/ml) | >240 |
| Methotrexate (25 mg/ml) | >240 |
| Mitomycin C (0.5 mg/ml) | >240 |
| Mitoxantrone (2.0 mg/ml) | >240 |
| Paclitaxel (Taxol) (6.0 mg/ml) | >240 |
| Thiotepa (10.0 mg/ml) | >240 |
| Vincristine Sulfate (1.0 mg/ml) | >240 |

**Please note that the following drug - Carmustine has extremely short permeation times of 15.1 minutes.**

6.2 Device Name: Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
This glove has been tested for use with specific chemotherapy drugs listed below.

**Chemotherapy Drug Permeation**
**(Minimum Breakthrough Detection Time in Minutes)**

| | |
|---|---|
| **Carmustine (BCNU) (3.3 mg/ml)** | 17.9 |
| Cisplatin (1.0 mg/ml) | >240 |
| Cyclophosphamide (Cytoxan) (20 mg/ml) | >240 |
| Cytarabine (100 mg/ml) | >240 |
| Dacarbazine (DTIC) (10.0 mg/ml) | >240 |
| Doxorubicin Hydrochloride (2.0 mg/ml) | >240 |
| Etoposide (20.0 mg/ml) | >240 |
| Fluorouracil (50.0 mg/ml) | >240 |
| Ifosfamide (50.0 mg/ml) | >240 |
| Methotrexate (25 mg/ml) | >240 |
| Mitomycin C (0.5 mg/ml) | >240 |
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| Paclitaxel (Taxol) (6.0 mg/ml) | >240 |
| Thiotepa (10.0 mg/ml) | >240 |
| Vincristine Sulfate (1.0 mg/ml) | >240 |

**Please note that the following drug - Carmustine has extremely short permeation times of 17.9 minutes.**

**7.0 Summary of the Technological Characteristics of the Device:**

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs posses the following technological characteristic (as compared to ASTM or equivalent standards):

| Characteristic | Standards Requirements | Results Summary | Conclusions |
|---|---|---|---|
| Dimensions | ASTM D6319-10 | Length ≥ 270mm<br>Palm Thickness ≥ 0.10mm<br>Finger Thickness ≥ 0.10mm<br>Width X-Small 70-80mm<br>Small 80-90mm<br>Medium 90-100mm<br>Large 101-111mm<br>X-Large ≥ 111mm | Meets Standard Requirements |
| Physical Properties | ASTM D6319-10 | Before Aging / After Aging<br>Tensile Strength ≥ 14 MPA / ≥ 14 MPA<br>Elongation ≥ 500% / ≥ 400% | Meets Standard Requirements |
| Freedom from pinholes | ASTM D5151-11<br>ASTM D6319-10 | Tested in accordance with ASTM D5151 test method. Pass quality level at G1 AQL 1.5 | Meets Standard Requirements |
| Powder Free Residue | ASTM D6124-11<br>ASTM D6319-10 | Result generated values ≤ 2 mg of residual powder per glove | Meets Standard Requirements |
| Biocompatibility | Dermal Sensitization (as ISO 10993-10:2010) | Not a contact skin sensitizer | Meets Standard Requirements |
| | Primary Skin Irritation Test (as ISO 10993-10:2010) | Not a primary skin irritant | Meets Standard Requirements |
| Chemotherapy Drugs Permeation Test Method | ASTM D6978-05 | **Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs**<br><br>Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes)<br>**Carmustine (3.3 mg/ml) 15.1**<br>Cisplatin (1.0 mg/ml) >240<br>Cyclophosphamide (20 mg/ml) >240<br>Cytarabine (100 mg/ml) >240<br>Dacarbazine (DTIC) (10.0 mg/ml) >240<br>Doxorubicin Hydrochloride (2.0 mg/ml) >240<br>Etoposide (20.0 mg/ml) >240<br>Fluorouracil (50.0 mg/ml) >240<br>Ifosfamide (50.0 mg/ml) >240<br>Methotrexate (25 mg/ml) >240<br>Mitomycin C (0.5 mg/ml) >240<br>Mitoxantrone (2.0 mg/ml) >240<br>Paclitaxel (Taxol) (6.0 mg/ml) >240<br>Thiotepa (10.0 mg/ml) >240<br>Vincristine Sulfate (1.0 mg/ml) >240 | Tested for Use with Chemotherapy Drugs. Carmustine has extremely short permeation times of 15.1 minutes. |

| Characteristic | Standards Requirements | Results Summary | Conclusions |
|---|---|---|---|
| Chemotherapy Drugs Permeation Test Method | ASTM D6978-05 | **Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs**<br><br>Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes)<br>Carmustine (3.3 mg/ml) 17.9<br>Cisplatin (1.0 mg/ml) >240<br>Cyclophosphamide (20 mg/ml) >240<br>Cytarabine (100 mg/ml) >240<br>Dacarbazine (DTIC) (10.0 mg/ml) >240<br>Doxorubicin Hydrochloride (2.0 mg/ml) >240<br>Etoposide (20.0 mg/ml) >240<br>Fluorouracil (50.0 mg/ml) >240<br>Ifosfamide (50.0 mg/ml) >240<br>Methotrexate (25 mg/ml) >240<br>Mitomycin C (0.5 mg/ml) >240<br>Mitoxantrone (2.0 mg/ml) >240<br>Paclitaxel (Taxol) (6.0 mg/ml) >240<br>Thiotepa (10.0 mg/ml) >240<br>Vincristine Sulfate (1.0 mg/ml) >240 | Tested for Use with Chemotherapy Drugs. Carmustine has extremely short permeation times of 17.9 minutes. |

## 8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs have been tested against the applicable ASTM standards listed above, and meet the requirements set forth in those standards.

There is no difference between the Proposed Devices and the Predicate Device with respect to performance standard and technological characteristics.

There is difference in colorant used in one of the Proposed Device (Orange), compared with Predicate Device (Blue). However, the difference does not affect the safety and effectiveness of the Proposed Device (Orange), as the Proposed Device (Orange) tested and passed Biocompatibility test, similar with Predicate Device.

The Proposed Devices were tested for 15 drugs, while the Predicate Device was tested for 12 drugs. The respective drug's permeation result is shown in Indication for Use of the Proposed Devices. The difference in labeling (with additional drugs tested, exceed ASTM D6978-05 requirements), and in Indications for Use do not affect the safety and effectiveness of the proposed devices.

## 9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

## 10.0 Conclusion

It can be concluded that the Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs are substantially equivalent to the predicate device identified in this 510(k) summary.

The Substantial Equivalent Comparison Table below outlines the similarity, and/or differences between the proposed devices and the predicate device for the substantial equivalent determination.

As such, this device is substantially equivalent to predicate device.

**Substantial Equivalent Comparison Table**

| **Characteristics** | **Predicate Device**<br>K091652 Nitrile Powder Free Examination Gloves (Blue) Tested for Use with Chemotherapy Drugs–VBLU | **Proposed Device (Blue)**<br>Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs | **Predicate Device**<br>K091652 Nitrile Powder Free Examination Gloves (Blue) Tested for Use with Chemotherapy Drugs-VBLU | **Proposed Device (Orange)**<br>Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs |
|---|---|---|---|---|
| Device Description/ Regulation Number | Patient Examination Glove/ 21 CFR Part 880.6250 | Substantial Equivalent | Patient Examination Glove/ 21 CFR Part 880.6250 | Substantial Equivalent |
| Product Code | 80 LZA, 80 LZC | 80 LZA, 80 LZC | 80 LZA, 80 LZC | 80 LZA, 80 LZC |
| Intended Use | Intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. | Substantial Equivalent | Intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. | Substantial Equivalent |

| **Characteristics** | **Predicate Device**<br>K091652 Nitrile Powder Free Examination Gloves (Blue) Tested for Use with Chemotherapy Drugs-VBLU | **Proposed Device (Blue)**<br>Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs | **Predicate Device**<br>K091652 Nitrile Powder Free Examination Gloves (Blue) Tested for Use with Chemotherapy Drugs-VBLU | **Proposed Device (Orange)**<br>Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs |
|---|---|---|---|---|
| Indications for Use | The Nitrile Examination Glove (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The list of chemotherapy drugs tested (with breakthrough times) are as follows:-<br><br>Chemotherapy Drugs<br>Breakthrough Time (Minutes)<br><br>Carmustine 6.60<br>Cisplatin >240<br>Cyclophosphamide (Cytoxan) >240<br>Dacarbazine >240<br>Doxorubicin Hydrochloride >240<br>Etoposide >240<br>Fluorouracil >240<br>Methotrexate >240<br>Mitomycin C >240<br>Paclitaxel >240<br>Thiotepa 14.83<br>Vincristine Sulfate >240<br><br>**Warning: Do not use with Carmustine and Thiotepa.** | A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.<br>This glove has been tested for use with specific chemotherapy drugs listed below.<br><br>Chemotherapy Drug Permeation<br>(Minimum Breakthrough Detection Time in Minutes)<br><br>**Carmustine (3.3 mg/ml) 15.1**<br>Cisplatin (1.0 mg/ml) >240<br>Cyclophosphamide (20mg/ml) >240<br>Cytarabine (100 mg/ml) >240<br>Dacarbazine (DTIC) (10.0 mg/ml) >240<br>Doxorubicin Hydrochloride (2.0 mg/ml) >240<br>Etoposide (20.0 mg/ml) >240<br>Fluorouracil (50.0 mg/ml) >240<br>Ifosfamide (50.0 mg/ml) >240<br>Methotrexate (25 mg/ml) >240<br>Mitomycin C (0.5 mg/ml) >240<br>Mitoxantrone (2.0 mg/ml) >240<br>Paclitaxel (Taxol) (6.0 mg/ml) >240<br>Thiotepa (10.0 mg/ml) >240<br>Vincristine Sulfate (1.0 mg/ml) >240<br><br>**Please note that the following drug - Carmustine has extremely short permeation times of 15.1 minutes.** | The Nitrile Examination Glove (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The list of chemotherapy drugs tested (with breakthrough times) are as follows:-<br><br>Chemotherapy Drugs<br>Breakthrough Time (Minutes)<br>Carmustine 6.60<br>Cisplatin >240<br>Cyclophosphamide (Cytoxan) >240<br>Dacarbazine >240<br>Doxorubicin Hydrochloride >240<br>Etoposide >240<br>Fluorouracil >240<br>Methotrexate >240<br>Mitomycin C >240<br>Paclitaxel >240<br>Thiotepa 14.83<br>Vincristine Sulfate >240<br><br>**Warning: Do not use with Carmustine and Thiotepa.** | A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.<br>This glove has been tested for use with specific chemotherapy drugs listed below.<br><br>Chemotherapy Drug Permeation<br>(Minimum Breakthrough Detection Time in Minutes)<br><br>**Carmustine (3.3 mg/ml) 17.9**<br>Cisplatin (1.0 mg/ml) >240<br>Cyclophosphamide (20 mg/ml) >240<br>Cytarabine (100 mg/ml) >240<br>Dacarbazine (DTIC) (10.0 mg/ml) >240<br>Doxorubicin Hydrochloride (2.0 mg/ml) >240<br>Etoposide (20.0 mg/ml) >240<br>Fluorouracil (50.0 mg/ml) >240<br>Ifosfamide (50.0 mg/ml) >240<br>Methotrexate (25 mg/ml) >240<br>Mitomycin C (0.5 mg/ml) >240<br>Mitoxantrone (2.0 mg/ml) >240<br>Paclitaxel (Taxol) (6.0 mg/ml) >240<br>Thiotepa (10.0 mg/ml) >240<br>Vincristine Sulfate (1.0 mg/ml) >240<br><br>**Please note that the following drug - Carmustine has extremely short permeation times of 17.9 minutes.** |

**TOP CALIBRE SDN. BHD.**

| **Characteristics** | **Predicate Device**<br>K091652 Nitrile Powder Free Examination Gloves (Blue) Tested for Use with Chemotherapy Drugs–VBLU | **Proposed Device (Blue)**<br>Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs | **Predicate Device**<br>K091652 Nitrile Powder Free Examination Gloves (Blue) Tested for Use with Chemotherapy Drugs-VBLU | **Proposed Device (Orange)**<br>Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs |
|---|---|---|---|---|
| Materials | Nitrile | Substantial Equivalent | Nitrile | Substantial Equivalent |
| Color | Blue | Substantial Equivalent | Blue | Orange |
| Design | Ambidextrous, in different sizes per ASTM D6319 dimension requirement. | Substantial Equivalent | Ambidextrous, in different sizes per ASTM D6319 dimension requirement. | Substantial Equivalent |
| Performance<br>I. Sterility<br>II. Freedom from holes<br>III. Dimension<br>IV. Physical Properties<br>V. Powder Free Residue | <br>Not Applicable (Non-Sterile)<br>Passes at AQL 1.5<br>Meets ASTM D6319<br>Meets ASTM D6319<br>Meets ≤ 2 mg/glove | <br>Substantial Equivalent<br>Passes at AQL 1.5 (Substantial Equivalent)<br>Meets ASTM D6319 (Substantial Equivalent)<br>Meets ASTM D6319 (Substantial Equivalent)<br>Meets ≤ 2 mg/glove (Substantial Equivalent) | <br>Not Applicable (Non-Sterile)<br>Passes at AQL 1.5<br>Meets ASTM D6319<br>Meets ASTM D6319<br>Meets ≤ 2 mg/glove | <br>Substantial Equivalent<br>Passes at AQL 1.5 (Substantial Equivalent)<br>Meets ASTM D6319 (Substantial Equivalent)<br>Meets ASTM D6319 (Substantial Equivalent)<br>Meets ≤ 2 mg/glove (Substantial Equivalent) |
| Single Use | Yes | Substantial Equivalent | Yes | Substantial Equivalent |
| Biocompatibility Test | Passes<br>i. Primary Skin Irritation Test<br>ii. Dermal Sensitization Test | <br>Not an irritant<br>Not a contact sensitizer | Passes<br>i. Primary Skin Irritation Test<br>ii. Dermal Sensitization Test | <br>Not an irritant<br>Not a contact sensitizer |
| Packaging | Packed in Dispenser Boxes | Substantial Equivalent | Packed in Dispenser Boxes | Substantial Equivalent |
| Labeling Claim | Tested For Use with Chemotherapy Drugs | Substantial Equivalent | Tested For Use with Chemotherapy Drugs | Substantial Equivalent |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 8, 2014

Top Calibre Sdn. Bhd.
Ms. Rosnita Maodin
Quality Assurance Manager
Lot 13726, Jalan Haji Salleh, Batu 5 ¼ , Off Jalan Meru
Klang, Selangor
MALAYSIA 41050

Re: K133949
Trade/Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-sterile, Tested for Use with Chemotherapy Drugs and Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-sterile, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: March 3, 2014
Received: March 6, 2014

Dear Ms. Maodin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

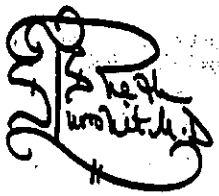
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):**

**Device Name:** Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

**Indications for Use:**

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
This glove has been tested for use with specific chemotherapy drugs listed below.

**Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes)**

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| Methotrexate (25 mg/ml) | > 240 |
| Mitomycin C (0.5 mg/ml) | > 240 |
| Mitoxantrone (2.0 mg/ml) | > 240 |
| Paclitaxel (Taxol) (6.0 mg/ml) | > 240 |
| Thiotepa (10.0 mg/ml) | > 240 |
| Vincristine Sulfate (1.0 mg/ml) | > 240 |

**Please note that the following drug - Carmustine has extremely short permeation times of 15.1 minutes.**

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office Of Device Evaluation (ODE)

Elizabeth F. Claverie -S
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# Indications for Use

**510(k) Number (if known):**

**Device Name:** Powder Free Nitrile Patient Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

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**Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes)**

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|---|---|
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| Cyclophosphamide (Cytoxan) (20 mg/ml) | > 240 |
| Cytarabine (100 mg/ml) | > 240 |
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| Doxorubicin Hydrochloride (2.0 mg/ml) | > 240 |
| Etoposide (20.0 mg/ml) | > 240 |
| Fluorouracil (50.0 mg/ml) | > 240 |
| Ifosfamide (50.0 mg/ml) | > 240 |
| Methotrexate (25 mg/ml) | > 240 |
| Mitomycin C (0.5 mg/ml) | > 240 |
| Mitoxantrone (2.0 mg/ml) | > 240 |
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**Please note that the following drug - Carmustine has extremely short permeation times of 17.9 minutes.**

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office Of Device Evaluation (ODE)

Elizabeth F. Claverie -S
2014.04.07 23:46:05 -04'00'